MAY 17 2011

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: December 10, 2010

Submitter: GE Healthcare (GE Medical Systems *Information Technologies,* Inc.)
9900 Innovation Drive
Wauwatosa, WI 53226

Primary Contact Person: Joe Lucas
Regulatory Affairs – Diagnostic Cardiology
9900 Innovation Drive
Wauwatosa, WI 53226
T: (414) 721-2593
F: (414) 721-3863

Secondary Contact Person: Kristin Pabst
Regulatory Affairs – Diagnostic Cardiology
9900 Innovation Drive
Wauwatosa, WI 53226
T: (414) 721-3104
F: (414) 721-3863

Device: Trade Name: MAC 600 Resting ECG Analysis System

Common/Usual Name: MAC 600

Classification Names: Product Code:

21 CFR	Classification Name	Code
870.2340	Electrocardiograph	DPS
870.1425	Programmable Diagnostic Computer	DQK
870.2920	Transmitters and Receivers, Electrocardiographs, Telephone	DXH

Predicate Device(s): K073625 MAC 5500 RESTING ECG ANALYSIS SYSTEM

Device Description: The MAC 600 Resting ECG Analysis System is intended to perform ECG acquisition, analysis and recording. It can display 3, 6 or 12 leads of ECG data and can print the ECG data 3 leads at a time. The MAC 600 will provide, in resting ECG mode, ECG quality information using the hookup advisor that advises users of poor lead quality based on noise measurement. The MAC 600 can be upgraded to provide software analysis options such as 12-lead interpretive analysis and 12-lead resting ECG measurement and interpretation utilizing the Marquette 12SL ECG Analysis program (K060833). Transmission of ECG data to a central ECG cardiovascular information system is also optional.

The MAC 600 delivers multiple leads of ECG on reports and includes a numeric keypad, and function keys for entering patient ID and other data entry. There is an integrated 4.3" color display, and an integrated thermal writer. The thermal writer will print real time continuous waveform, alphanumeric data and non-real time reports. The device

has removable memory storage to store resting ECG records. The device also can export the resting ECG record to an XML or PDF file on an SD card. The MAC 600 can be run off of a rechargeable lithium-ion battery to allow it to be used as a portable unit.

Intended Use: The MAC 600 Resting ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information for adult and pediatric populations. Basic systems deliver 3 or 12 lead ECGs, and can be upgraded to provide software analysis options such as interpretive analysis of the electrocardiogram. Transmission of ECG data to a central ECG cardiovascular information system is optional.

The MAC 600 is intended to be used by trained operators in a hospital or medical professional's facility environment as well as used in clinics, physician offices, outreach centers or wherever ECG testing is performed to record ECG signals from surface electrodes.

Contra-indications

1. MAC 600 is not intended for use as a vital signs physiological monitor.
2. MAC 600 is not intended for use during patient transport.
3. MAC 600 is not intended for intra cardiac application.
4. MAC 600 is not intended for use with high frequency surgical units.

Technology: The MAC 600 Resting ECG Analysis System employs the same functional scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The MAC 600 Resting ECG Analysis System and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, MAC 600 Resting ECG Analysis System, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the MAC 600 Resting ECG Analysis System to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

GE Medical Systems Information Technologies, Inc
c/o Mr. Joe
Regulatory Affairs
9900 Innovation Drive
Wauwatosa, WI 53226

MAY 17 2011

Re: K103765
Trade/Device Name: MAC 600 Resting ECG Analysis System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: December 20, 2011
Received: February 18, 2011

Dear Mr. Lucas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K103765

Device Name: MAC 600

Indications for Use:

The MAC 600 Resting ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information for adult and pediatric populations. Basic systems deliver 3 or 12 lead ECGs, and can be upgraded to provide software analysis options such as interpretive analysis of the electrocardiogram.
Transmission of ECG data to a central ECG cardiovascular information system is optional.
The MAC 600 is intended to be used by trained operators in a hospital or medical professional's facility environment as well as used in clinics, physician offices, outreach centers or wherever ECG testing is performed to record ECG signals from surface electrodes.

Contra-indications

1. MAC 600 is not intended for use as a vital signs physiological monitor.
2. MAC 600 is not intended for use during patient transport.
3. MAC 600 is not intended for intra cardiac application.
4. MAC 600 is not intended for use with high frequency surgical units.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K103765